



HOW TO USE PLAIN LANGUAGE

This is a controlled document. It should not be altered in any way without the express permission of the author and the approver. Queries or requests for changes can be made to Maryanne.Turner@petermac.org.

Version History

Version: 1.0
Approved Date: 29 Nov 2021
Supersedes: NA

Author and Editors

Version 1.0, 29 Nov 2021, Maryanne Turner, Stephen Luen and Adrian Minson

Approver

Professor Mark Rosenthal, Parkville Cancer Clinical Trials Unit Director

Signature: 
mark.rosenthal (Nov 29, 2021 14:45 GMT+11)

Date: Nov 29, 2021

Endorsed for Use by

Parkville Cancer Clinical Trials Unit

Peter Mac Human Research Ethics Committee and Governance Office

Royal Melbourne Hospital Human Research Ethics Committee and Governance Office

Monash Health Human Research Ethics Committee and Governance Office

Cancer Trials Australia

Guidance

The Plain Language Tool is a glossary of common cancer terms and sentence examples for research and clinical trial patient facing content. Language should:

- Be easily understood at reading level grade 8 or below (i.e. stops instead of inhibitor)
- Use active voice, where possible (i.e. standard treatment given for lung cancer or you will be randomly selected to receive one of the following treatments)
- Use short sentences, where possible
- Avoid subordinate clause sentences requiring additional sentences to explain the original concept
- Avoid acronyms, spell out terms where possible or in the first use



Plain Language Terms

Acute leukaemia	A type of cancer that affects immature cells in the blood and bone marrow
Advanced	Cancer has spread to other parts of your body and may not be able to cured
Locally advanced	Cancer has grown outside area/organ it started in, but has not yet spread to other parts of the body
Allogeneic	Cells are collected from another person's blood or bone marrow (donor)
Allogeneic Bone Marrow Transplant	<p>A procedure where the patient is given bone marrow or stem cells from another person (donor) to treat a number of different blood and bone marrow diseases</p> <p>Or</p> <p>You will be given bone marrow or stem cells from another person (donor) to treat your blood or bone marrow disease</p>
Anaplastic lymphoma kinase positive (ALK positive)	ALK positive (ALK+) changes can cause cancer cells to grow and spread to other parts of your body
Androgen Deprivation Therapy (ADT)	Prostate cancer cells usually require hormones, such as testosterone, to grow. Androgen Deprivation Therapy (ADT) is a type of anti-hormone treatment used to treat prostate cancer. ADT works by reducing the levels of hormones to prevent the prostate cancer cells from growing
Antibody	An antibody is a protein made by the body as part of the immune response to a foreign substance (such as bacteria, virus / infection)
Monoclonal antibody	A monoclonal antibody is a type of antibody (protein made by the body as part of the immune response to a foreign substance) made in a laboratory designed to bind specifically to cancer cells. When used in anti-cancer treatments, the monoclonal antibody delivers the treatment directly to cancer cells
Anti programmed death 1 (Anti PD-1)	Anti-PD-1 antibodies work by stopping specific proteins that reduce the ability of the body's immune system to attack cancer cells. Stopping these proteins is expected to help immune cells attack cancer cells
Autologous	Cells are collected from your own blood or bone marrow



BCL2	BCL2 is a protein that helps control whether a cell lives or dies by a process called apoptosis. BCL2 changes can protect cancer cells from dying when receiving anti-cancer treatments
Bromodomain and extraterminal domain (BET)	Bromodomain and extraterminal domain (BET) are proteins that can play a role in the growth of some cancers
Bromodomain and extraterminal domain (BET) inhibitor	Bromodomain and extraterminal domain (BET) are proteins that can play a role in the growth of some cancers. BET inhibitors work by stopping BET changes that can cause increased growth of cancer cells
Biomarker	A biomarker is a biological characteristic that can be measured and which can indicate the behaviour of the cancer
Blast cells	Blast cells are immature white blood cells not normally visible in healthy blood. Acute leukaemia is identified by the increase of abnormal blast cells that take over the bone marrow and often spill out into the bloodstream
Blinded	You won't know what treatment you are receiving
Double-blinded	You and your clinical trial doctor will not know which treatment you are receiving
BRAF	The BRAF gene sends messages inside cells to tell them how to grow. In some cancers, changes in the BRAF gene can cause the cancer to grow
BRAF V600	BRAF V600 is a change in the BRAF gene that leads to an increase in the growth and spread of cancer cells
Breast cancer gene 1 (BRCA1) and breast cancer gene 2 (BRCA2)	Breast cancer gene 1 (BRCA1) and breast cancer gene 2 (BRCA2) play a role in repairing damaged DNA. Changes in BRCA1 and BRCA2 can increase your risk of developing cancer and can cause cancers to grow
Bruton tyrosine kinase (BTK)	Bruton tyrosine kinase (BTK) is a gene that is important in the growth of B-cells (type of white blood cell, part of the immune system). Changes in this BTK gene can cause primary immunodeficiency (when the immune system does not work properly)
Bruton tyrosine kinase (BTK) inhibitor	Bruton tyrosine kinase (BTK) is a gene that is important in the growth of B-cells (type of white blood cell, part of the immune system). Changes in this BTK gene can cause primary immunodeficiency (when the immune system



does not work properly). BTK inhibitors work by blocking the BTK gene with a drug to stop the growth of some B-cell cancers

Cancer of unknown primary (CUP)

Cancer of unknown primary (CUP) is a rare condition in which cancer cells are found in the body but the place the cancer began is not known

Chimeric antigen receptor T cell therapy (CAR T)

Chimeric antigen receptor T cell therapy (CAR T) is a new form of immunotherapy where T cells, collected from you or a donor's blood, are genetically changed to precisely target cancer cells

Chemotherapy

Chemotherapy is a type of treatment that works to stop the growth of cancer cells, either by killing the cells or by stopping them from making copies of themselves

Chronic leukaemia

Chronic Leukaemia is a type of cancer of the blood and bone marrow, which often progresses/grows more slowly than other types of leukaemia

Dose escalation

The dose escalation phase of a clinical trial tests the new treatment at different dose levels to find the best and safest dose to give patients

Dose expansion

The dose expansion phase of a clinical trial follows the dose escalation phase. Once the best and safest dose of a new treatment is found, this treatment dose is then given to a larger group of patients to test how effective the treatment is against cancer

Eligibility criteria

Clinical trials have a set of eligibility criteria that you need to meet before joining a clinical trial. Eligibility criteria may include age, medical history and current health status. These criteria make sure that patients who are more likely to experience serious side effects are not put at risk

Oestrogen receptor positive (ER+)

Oestrogen receptor positive (ER+) breast cancer is sensitive to the hormone oestrogen, which can cause the cancer cells to grow. Hormone treatments that block oestrogen can be effective in treating ER+ breast cancer

Expanded Access

Also called compassionate use, expanded access allows patients to access new treatments, and medical devices used to diagnose, monitor, or treat patients with a medical condition that would not normally be available to them

Fibroblast growth factor receptors (FGFR)

Fibroblast growth factor receptors (FGFR) are proteins, which send messages inside cells to tell them how to grow. In some cancers, changes in these genes can cause the cancer to grow



Lower Gastro-Intestinal Cancer	Cancers of the lower part of the digestive system. This includes the bowel, colon and rectum
Upper Gastro-Intestinal Cancer	Cancers of the first part of the digestive system. This includes the throat, stomach, small bowel, liver, pancreas and gall bladder
Gynaecological Cancer	Cancer of the female reproductive system. This includes the endometrium, cervix, ovaries and vagina.
Human epidermal growth factor receptor 2 (HER2)	Human epidermal growth factor receptor 2 (HER2) is a protein found on cells in the body that control how cells grow. High levels of HER2 (called HER2+) in cancer, causes it to grow. Targeting HER2 can help slow cancer growth
Hodgkin lymphoma	Hodgkin lymphoma is a type of cancer of the lymphatic system (part of the immune system). In Hodgkin lymphoma, cells in the lymphatic system grow abnormally and can spread.
Aggressive non-Hodgkin lymphoma	Aggressive non-Hodgkin lymphoma is a group of aggressive cancers (fast growing), which affects white blood cells (part of the immune system). This usually starts in lymph nodes or other lymph tissue, but can sometimes affect other organs. There are two main types of non-Hodgkin lymphoma, B-cell lymphomas and T-cell lymphomas. B-cell lymphomas develop from B-cells in the lymphatic system and T-cell lymphomas develop from the T-cells in the lymphatic system.
Indolent Non-Hodgkin Lymphoma	Indolent non-Hodgkin lymphoma is a group of slow growing cancers, which affect white blood cells (part of the immune system). This usually starts in lymph nodes or other lymph tissue, but can sometimes affect other organs. There are two main types of non-Hodgkin lymphoma, B-cell lymphomas and T-cell lymphomas. B-cell lymphomas grow from B-cells in the lymphatic system and T-cell lymphomas develop from the T-cells in the lymphatic system.
HRAS	HRAS is a gene, which sends messages inside cells to direct their growth. In some cancers, changes in this gene causes the cancer to grow
Immunotherapy	Immunotherapy is a type of treatment which works with your immune system to help destroy cancer cells or stop them growing
Intravenous (IV) infusion	Treatment will be given in liquid form, by injection into your vein
JAK-2	JAK-2 is a gene involved in cell growth. Changes to JAK-2 can cause overproduction (make more than is needed or wanted) of bone marrow cells



leading to a number of conditions including polycythemia vera, essential thrombocytosis and myelofibrosis

KRAS KRAS is a gene that makes a protein involved in controlling cell growth, maturing and death

KRAS G12C KRAS G12C is a change in the KRAS gene that leads to an increase in the growth and spread of cancer cells

Metastatic Cancer that has spread to other parts of the body

Multiple myeloma Multiple myeloma is a type of cancer that affects the plasma cells found in the bone marrow

Mutation Changes in the genes of the cancer

Myelodysplastic syndromes (MDS) Myelodysplastic syndromes (MDS) is a group of cancers that affect the production of normal blood cells in the bone marrow

Myelofibrosis (MF) Myelofibrosis (MF) is a type of bone marrow cancer, which affects how the body makes blood cells

Or

Myelofibrosis (MF) is a type of bone marrow cancer, which affects how your body makes blood cells

Myeloproliferative Neoplasms (MPNs) Myeloproliferative Neoplasms (MPNs) is a group of blood cancers that cause the bone marrow stem cells to grow and reproduce abnormally

Neuro-oncology Cancer of the brain and spinal cord

Oral The treatment is taken by mouth

Palliative care Palliative care helps patients live their life as comfortably as possible when living with a life-limiting illness or are at end of life stages

PARP PARP is a type of protein in the body that helps to fix damaged cells

PARP inhibitor PARP inhibitor treatments work by stopping the PARP proteins from fixing damaged cancer DNA. This results in cancer cell death



PD-1 (programmed death 1)	PD-1 (programmed death 1) is a protein found on T cells (a type of immune cell) that helps keep your body's immune responses in check. When PD-1 is bound/joined to another protein called PD-L1, it helps keep T cells from killing other cells, including cancer cells. Treatments called immune checkpoint inhibitors, block PD-1. When this protein is blocked, the 'brakes' on the immune system are released and the ability of T cells to kill cancer cells is increased
PD-L1 (Programmed death-ligand 1)	PD-L1 (Programmed death-ligand 1) is a protein that helps keep immune cells from attacking certain cells in your body. Some cancers have high amounts of PD-L1. This can 'trick' the immune system into thinking cancer cells are not harmful and not attack them
/Personalised cancer vaccine (PCV)	A personalised cancer vaccine (PCV) is a type of treatment made by using your cancer cells to identify specific proteins that may help the immune system recognise cancer cells as bad
Phase one	A phase one clinical trial tests new treatments sometimes for the first time in humans, usually in a small group of patients. The aim of a phase one clinical trial is to test the safety of the new treatment and find the best dose to give patients
Phase one / two	A phase one / two clinical trial combines a phase one and two. The phase one tests new treatments sometimes for the first time in humans, usually in a small group of patients. The phase two part tests the new treatment in a larger group of patients with selected cancer types. The aim of a phase one / two is to find the best dose of the new treatment and see if it works against the cancer
Phase Two	A phase two clinical trial follows a phase one, in a large group of patients with selected cancer types. The aim of a phase two is to find out if the new treatment is effective in these cancer types
Phase two / three	A phase two / three clinical trial follows a phase one / two, in a larger group of patients with specific cancer types. The aim of a phase two / three is to compare the new treatment to existing treatments available for that cancer type and closely monitor patients to make sure the treatment is safe and effective in that cancer type
Phase three	A phase three clinical trial follows a phase two, in a larger group of patients with specific cancer types. The aim of a phase three is to compare the new treatment to existing treatments available for that cancer type.



Pilot	A pilot clinical trial gathers specific essential information and usually runs before a larger clinical trial. The aim of a pilot clinical trial is to increase the likelihood of success for future clinical trials
Placebo	Placebo is a pill/liquid that contains no active treatment
Proof of concept clinical trial	A proof of concept clinical trial is a certain way of testing an idea to see if it is useful, and can be applied in patient care
Progesterone receptor positive (PR+)	Progesterone receptor positive (PR+) breast cancer is sensitive to progesterone, which can cause cancer cells to grow. Hormone treatment that blocks progesterone can be effective in treating PR+ breast cancer
Prostate specific membrane antigen (PSMA)	Prostate specific membrane antigen (PSMA) is a type of protein found in higher amounts on the surface of prostate cancer cells. PSMA can be used to find prostate cancer cells that have come back or spread to other parts of the body
Lu-PSMA (prostate specific membrane antigen)	Lu-PSMA (prostate specific membrane antigen) is a type of precision radiation therapy that works by targeting the protein PSMA. If prostate cancer has spread to other parts of the body, PSMA will also be present in those areas. Lu-PSMA uses radiation to destroy all cancer cells expressing PSMA
Randomized	Randomly selected
Recurrence or Relapsed	Cancer has come back after treatment
Refractory	Cancer has not responded to treatment given
Relapsed platinum resistant or refractory high grade serous ovarian cancer (HGSOC)	Relapsed platinum resistant or refractory high grade serous ovarian cancer (HGSOC) is an advanced type of ovarian cancer that has come back after being treated with platinum-based chemotherapy treatment (such as cisplatin or carboplatin)
RET (rearranged during transfection)	Changes in the RET (rearranged during transfection) gene can cause cancer cells to grow and spread to other parts of the body
Sarcoma	Sarcoma is a type of cancer of the soft tissue or bone. This includes deep skin tissue, blood vessels, nerves, muscle, fat, bone and cartilage
Solid cancer	Cancer in the 'solid' organs such as breast or lung



Stem cell transplant	A stem cell transplant restores bone marrow and the immune system by giving stem cells to the patient
Allogeneic stem cell transplant	Stem cells given use the donor’s immune system to destroy cancer cells
Autologous stem cell transplant	Patients own stem cells, taken before treatment, are given back to restore bone marrow and immune system after high dose chemotherapy
Stereotactic radiotherapy (SRS)	A type of radiation therapy that precisely delivers radiation to a cancer tumour and none of the organs or tissue around it. This type of treatment increases the chance of only treating the cancer cells and not the healthy areas of the body
T cells	Part of the immune system. Their job is to kill foreign bodies, like bacteria or infection, and to help B cells produce antibodies
Transforming growth factor beta (TGFβ)	Too much transforming growth factor beta (TGFβ) is common in solid cancers, such as bladder and colon cancer and can help cancer grow, spread and avoid being attacked by your body’s immune system
Treatment naive	Not received treatment for their cancer
Tyrosine kinases (TKs)	A group of proteins in the body that control the growth of cells
ROS1, NTRK1, NTRK2, and NTRK3	ROS1, NTRK1, NTRK2, and NTRK3 are genes that tell the body to make certain tyrosine kinases (TKs). Changes in the ROS1, NTRK1, NTRK2, or NTRK3 genes can make too many TKs, or cause TKs to be overactive. This can cause cells to grow out of control and cancer can develop
Urological Cancer	Cancer of the urinary tract or male reproductive system. This includes cancers found in the kidney, ureter, bladder, prostate, testes or penis
Vascular endothelial growth factor (VEGF)	A protein that sends signals to increase the growth of new blood vessels, which can also increase the growth of cancer cells



Plain Language Sentence Examples

Primary outcome, opening sentence

A clinical trial to test the safety and effectiveness of the new treatment INSERT in patients with INSERT

Primary / secondary objectives

The aim of the clinical trial

Primary / secondary objective examples

Improve treatment outcomes

Improve the quality of life and health of patients

Test which treatment is better

Find the best dose of the new treatment INSERT and test how effectively it works on INSERT cancer

It is expected INSERT treatment will INSERT

It is expected this combination will work together to INSERT

Expected to kill the cancer cells

Stop cancer cells from growing and multiplying

Comparing investigational treatment to standard of care treatment

A clinical trial to test if the treatment INSERT is safe and better than the standard treatment given for INSERT cancer

This treatment (or treatment combination) will be compared against the standard treatment given for INSERT cancer

Comparing two treatments

A clinical trial to test if the treatment INSERT is better than INSERT in patients with INSERT cancer

Combination treatment

Treatment INSERT given with INSERT

It is believed that this new treatment combination may be able to INSERT

The combination of treatments is expected to work together to INSERT



This combination may improve treatment outcomes

Treatment mechanism of action	INSERT is a type of treatment called INSERT, which works by INSERT
Clinical trial design (dose escalation and expansion parts)	The clinical trial has two parts, the first will find the best dose of INSERT, the second will test INSERT in a larger group of patients to further test the safety and effectiveness of the treatment
Standard of care	Standard treatment (or treatment combination) given for patients with INSERT cancer
Randomisation to treatment arm	Patients are randomly selected to receive one of the following treatment arms:
Oral treatment inclusion criteria	Patient is able to swallow medication by mouth






Staff Guide - How To Use Plain Language V1.0

Final Audit Report

2021-11-29

Created:	2021-11-29
By:	Maryanne Turner (PCCTU.Feasibility@petermac.org)
Status:	Signed
Transaction ID:	CBJCHBCAABAA0AeGjo0epOSSvD4GAdZh-2fNwxM2w-vM

"Staff Guide - How To Use Plain Language V1.0" History

-  Document created by Maryanne Turner (PCCTU.Feasibility@petermac.org)
2021-11-29 - 3:05:07 AM GMT- IP address: 203.4.166.50
-  Document emailed to mark rosenthal (mark.rosenthal@petermac.org) for signature
2021-11-29 - 3:05:42 AM GMT
-  Email viewed by mark rosenthal (mark.rosenthal@petermac.org)
2021-11-29 - 3:45:15 AM GMT- IP address: 116.204.144.4
-  Document e-signed by mark rosenthal (mark.rosenthal@petermac.org)
Signature Date: 2021-11-29 - 3:45:31 AM GMT - Time Source: server- IP address: 116.204.144.4
-  Agreement completed.
2021-11-29 - 3:45:31 AM GMT